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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
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In re Application of	:
Crofts et al	:
Serial No.: 09/509,482	: Decision on Petition
Filed: 15 September 2000	:
Attorney Docket No. 1871-130	:

This letter is in response to the Request for Withdraw of Restriction Requirement mailed 6 March 2002.

BACKGROUND

This application was filed under 35 USC 371 as the national stage filing of PCT/AU98/00817.

In Paper No 7, mailed 10 December 2001, the Examiner restricted the claims into 9 Groups. He neglected to include claim 25 added by preliminary amendment on 15 September 2001 into any of the groupings. Furthermore, he objected to claim 18 as being improperly dependent and therefore did not include claim 18 in the original restriction. Groups I-III were drawn to DNA products comprising SEQ ID NOS. 1, 5 and 6, respectively, Group IV was drawn to a human protein, Group V was drawn to an antibody, Group VI to a transgenic animal, and Group VII-IX drawn to probes and anti-sense molecules complementary to SEQ ID NOS 1, 5 and 6 respectively.

The Examiner reasoned that the Groups I-IX did not have unity of invention because they lack a common utility which is based upon a common structural feature lacking from the prior art. Since the Examiner did not state the statutory basis for this decision, it appears from the record the Examiner was restricting the Application according to 35 USC 121 which is proper for a application filed under 35 USC 111.

In Paper No. 8, filed 11 February 2002, Applicants elected Group I with traverse. The traversal was on the grounds that polynucleotides and the transgenic animal made with the polynucleotides be examined together since the host cells encoding the polynucleotide should not be distinguished from the transgenic animal. In addition,

Applicant traversed the separation of the probes and anti-sense molecules from the encoding polynucleotides as the DNA molecules exists as a duplex in nature and as such share a common structural feature.

In Paper No. 10, mailed 18 April 2002, the Examiner considered the traversal but found it not persuasive. The Examiner argued a serious burden can be demonstrated by the separate classification of transgenic animals and polynucleotides. Further, the Examiner compared probes and coding strand interaction are analogous to receptor-ligand interaction and antibody-antigen interaction and since the nucleic acid probes can be used for a different function from the encoding polynucleotide strand, the two are distinct chemical compounds. The Examiner made the restriction Final.

In Paper No. 21 filed 4 June 2003, Applicants Petitioned under 37 CFR 1.181 to withdraw the Restriction Requirement. The Petition argued that the probes and anti-sense molecules of claims 19-20 be examined together with the appropriate encoding strand polynucleotide. Applicants requested Groups I and VIII, II and VIII, and III and IX be examined together, into three groups instead of 6.

DISCUSSION

The current application was filed under 35 USC 371, so a proper examination of the application would have led the Examiner to restrict the application according to 35 U.S.C. 121 and 372, identify why the groups did not share a special technical feature and therefore lacked unity of invention.

Applicant failed to notice the 35 USC 371 filing status of the Application and did not address their arguments under PCT Rule 13.

In view of facilitating a clear prosecution history the following Lack of Unity requirement on the instantly pending claims is being set forth below:

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 1-4, 9-14, 19-24 and 26-29, drawn to polynucleotides encoding a vitamin D receptor comprising exon 1d or a fragment thereof, vectors and host cells expressing said polynucleotides and complementary nucleotides of exon 1d or fragments thereof including probes to exon 1d and antisense molecules to exon 1d.

Group II, claim(s) 5-8, 19-20 and 25, drawn to polynucleotides encoding a vitamin D receptor comprising exon 1f, 1e, or fragments thereof or exons 1f and 1e or fragments thereof, plasmid or expression vectors comprising said polynucleotides and complementary nucleotides of exon 1f, 1e or fragments thereof or 1f and 1e or fragments

thereof including probes to exons 1f or 1e or 1f and 1e and antisense molecules to exons 1f or 1e or 1f and 1e.

Group III, claim 15, drawn to a human vitamin D receptor polypeptide.

Group IV, claim 16, drawn to an antibody to a human vitamin D receptor polypeptide.

Group V. Claim 17, drawn to a transgenic animal with a human vitamin D receptor expressed therein.

Claim 18 as presently recited is an improper dependent claim for not having recited a multiply dependent claim in the alternative. Therefore claim 18 is not included in the current lack of unity.

The special technical feature of Group I is the specific vitamin D isoform comprising exon 1d and probes to that exon 1d.

The special technical feature of Group II is the specific vitamin D isoform comprising exon 1f or 1e or 1f and 1e and probes to exons 1f or 1e or 1e and 1f.

The special technical feature of Group III is a specific polypeptide encoded by a vitamin D receptor polynucleotide .

The special technical of Group IV is an antibody that specifically binds any vitamin D receptor polypeptide.

The special technical feature of Group V is a transgenic animal transformed with a vitamin D receptor polynucleotide.

4. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: MacDonald et al., (of record teaches a polynucleotide that encodes for a human vitamin D receptor, thereby teaching Applicant's invention as presently recited in claim 1 and 15. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

It is noted that the full scope of Applicant's presently recited claim read upon any human vitamin D receptor. The probes and antisense molecules are limited to having unity of invention inasmuch as they hybridize to exons 1d or 1e or 1f or 1e and 1f, since as Applicant has readily admitted in their specification and in Figure 1 that exons 2-9 are identical in all of the prior art and the presently recited vitamin D receptor polynucleotides claimed in claims 1-9 and 19-25.

Applicant has requested rejoinder of claims 19 and 20 with Groups I and II and III, as claims 19 and 20 read upon the polynucleotides encoding a vitamin D receptor comprising exon 1d, Group I, exon 1f, Group II and exon 1e, Group III.

Group I will be examined as it now includes claims 1-4, 9-14, 19-24 and 26-29, drawn to an invention of polynucleotides encoding a vitamin D receptor comprising exon 1d or a fragment thereof, vectors and host cells expressing said polynucleotides and complementary nucleotides of exon 1d or fragments thereof including probes to exon 1d and antisense molecules to exon 1d. The Finality of the Office action mailed 4-22-03 is hereby removed and an action on the new Group of claims will be forthcoming.

DECISION

This request is **GRANTED** for the reasons set forth above.

The application is being forwarded to the examiner for action not inconsistent with this decision.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, Washington DC 20231 or by telephone at (703) 308-7553 or by facsimile transmission at (703) 305-7230.

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